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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/480,472	06/06/1995	SHERROL H. MCDONOUGH	213/066	9286

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EXAMINER

MARSCHER, ARDIN H

ART UNIT PAPER NUMBER

1631

DATE MAILED: 06/17/2003

51

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

08/480,472

Applicant(s)

McDonough et al.

Examiner

Ardin Marschel

Art Unit

1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 2/5/03 and 2/7/03
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) See attached list. is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) See attached list. is/are allowed.
- 6) ☒ Claim(s) See attached list. is/are rejected.
- 7) ☒ Claim(s) 48-51, 54, 93, 99, 220, and 221 is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on Nov 26, 2002 is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: See attached claim status listing.

CLAIM STATUS LISTING FOR OFFICE ACTION, PAPER NO. 51

CLAIMS PENDING:

39-42, 48-51, 54-56, 67-73, 75, 78-80, 82-84, 86, 88-90, 92, 93, 95, 96, 98-162, 164-174, and 176-231

CLAIMS ALLOWED:

42, 55, 56, 75, 78-80, 82, 83, 95, 96, 100-149, 151-157, 164-166, 169-172, 174, 177-179, 185, 187-191, 195, 196, 199-203, 216-219, and 227-231

CLAIMS REJECTED:

39-41, 67-73, 84, 86, 88-90, 92, 98, 150, 158-162, 167, 168, 173, 176, 180-184, 186, 192-194, 197, 198, 204-215, and 222-226

CLAIMS OBJECTED TO:

48-51, 54, 93, 99, 220, and 221

CLAIMS CANCELED:

1-38, 43-47, 52, 53, 57-66, 74, 76, 77, 81, 85, 87, 91, 94, 97, 163, and 175

Applicants' arguments, filed 2/5/03 and 2/7/03, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

VAGUENESS AND INDEFINITENESS:

Claims 167, 214, and 215 are rejected, as discussed below, under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

This rejection is reiterated from the previous office action, mailed 8/28/02. It is noted that the above listed claim cites the phrase "the sequence perfectly complementary thereto". This phrase causes the claim to be vague and indefinite as to the metes and bounds of it as set forth in the previous office action, mailed 8/28/02. It is noted that claim 167, lines 6-7, still contains this unclear phrase. Clarification via clearer claim wording is requested.

Claims 214 and 215 depend from canceled claim 163 which thus makes them vague and indefinite as to their content.

REJECTIONS BASED ON PRIOR ART

The following is a quotation of the appropriate paragraphs

of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(e) the invention was described in-

(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or

(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

Claim 167 is rejected under 35 U.S.C. § 102(e)(2) as being clearly anticipated by Shah et al. (P/N 5,521,300).

This rejection is reiterated from the previous office action, mailed 8/28/02, as being rejected due to the above unclarity in claim 167 which remains therein as described in the previous office action, mailed 8/28/02.

The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been

obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103(a).

Claims 39-41, 67-73, 84, 86, 88-90, 92, 98, 150, 158-162, 168, 173, 176, 180-184, 186, 192-194, 197, 198, 204-213, and 222-226 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Boddington et al. [J. Clin. Microbiol. (1990) 28:1751] taken in view of Suzuki et al. [J. of Bact. (1988) 170(6):2886].

This rejection is reiterated from the previous office action, mailed 8/28/02, including certain newly added claims as well as certain added claims as being within the metes and bounds of previously rejected claims. Applicants firstly argues that Boddington et al. does not disclose any relevant sequences as presently claimed as probe or primer sequences. In response this argument is moot as being directed only to Boddington et al. whereas, in contrast, the rejection is based on the combination of the above two listed references wherein relevant sequences are described in Suzuki et al. and not in Boddington et al. Applicants then indicate that various sequences are present

within the 16S rRNA sequence as given in Suzuki et al. This is acknowledged as apparently agreed with by applicants. Applicants then repeat an aspect of the basis of this rejection which is also acknowledged. Applicants then argue that Suzuki et al. does not disclose a probe or primer of the present invention. This argument is also moot as being directed to Suzuki et al. alone whereas, in contrast, the rejection is based on the above listed combination of references wherein probes and primers are suggested and motivated in Boddinhaus et al. as being defined by sequence differences as set forth in Suzuki et al. Applicants then argue that probing and priming has not been suggested or motivated in the references. In response the sequence differences has been described as motivating and suggesting the design of probes or primers as set forth in Boddinhaus et al. in combination with Suzuki et al. wherein such sequence differences are shown. Applicants then argue that there is no clinically relevant reason for distinguishing between organisms that has been set forth as the basis for this rejection. In response, the clinical relevance has not been set forth nor is required for probe or primer design which has been, however, motivated and suggested for Mycobacterial detection as set forth in the previous office action, mailed 8/28/02.

Claims 48-51, 54, 93, 99, 220, and 221 are objected to as being dependent upon a rejected base claim, but would be

allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 42, 55, 56, 75, 78-80, 82, 83, 95, 96, 100-149, 151-157, 164-166, 169-172, 174, 177-179, 185, 187-191, 195, 196, 199-203, 216-219, and 227-231 are allowed.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703)308-4242 or (703)305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ardin Marschel, Ph.D., whose telephone number is (703)308-3894. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (703)308-4028.

Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instrument Examiner, Tina Plunkett, whose telephone number is (703)305-3524 or to the Technical Center receptionist whose telephone number is (703)308-0196.

June 13, 2003

Ardin H. Marschel
ARDIN H. MARSCHEL
PRIMARY EXAMINER